THE CANCER NEWSLETTER

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HEW Approves New Cancer Clinical Education Grants, Without Trainee Stipends; $4 Million Available In '75

NCI has redesigned its clinical education program, taking out the stipends for trainees, and won HEW approval for a new $4 million a year effort to upgrade cancer-related education in health professions schools.

An announcement is being prepared to spell out details of the program, with a deadline of about Oct. 1 for applications for grants from fiscal 1975 appropriations.

The former program reached a peak of $7.5 million a year before it was ordered phased out when HEW decreed NIH could no longer support clinical training. Of that figure, $3.5 million went into trainee stipends, the rest to institutional support. Participating were 84 medical schools, 32 dental schools, five research institutions and five schools of osteopathy.

J. Palmer Saunders, director of the Div. of Research Resources & Centers, said $4 million for the program is in the President's 1975 budget. More money might be allocated for it if the number of good applications warrants it and if the NCI budget is increased above the $600 million requested by the President.

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IN BRIEF

NCI Thinks Puerto Rico Should Have Comprehensive Center; President Says He Won't Oppose NIH Budget Increases

PUERTO RICO is in line for a comprehensive cancer center designation, not in the next round of announcements coming up in June but perhaps in the one following. J. Palmer Saunders, director of NCI's Div. of Research Resources & Centers, said after a visit to the commonwealth that competing factions there are working on compromises to develop a coordinated effort in putting together a center program. The homogenous population, geographically contained, is a good location for certain types of studies. Follow up is easy, even with those patients who move to the mainland because of the close ties they maintain with relatives at home. . . .**PRESIDENT NIXON** won't oppose increases for NIH budgets by Congress; he indicated to visitors recently that he had expected Congress to increase NIH budget funds, so he submitted modest increases for NCI and the Heart & Lung Institute, virtually no increases for the other institutes knowing all would get more. . . .**WEINBERGER FELLOWSHIP** applications will be reviewed in time for processing by the June 30 deadline. The NIH Div. of Research Grants denied the report that it was overwhelmed by the number of applications and might lose some of the money appropriated for the program. . . . **SEARCH COMMITTEE** looking for a "world renowned" scientist to head basic research at Frederick Cancer Center has narrowed the list of prospects to 10. The committee expects to make its final recommendation between May 30 and July 15. . . .

New Cancer Clinical Education Program Approved; Faculty Salaries Eligible

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The program could use as much as $8 million if the money is available and applications are of high enough quality, Saunders said.

Applications will be competitive and will undergo peer review, Saunders said. Among other items eligible for support through the program will be faculty salaries. Although students may not receive stipends as such, they may be paid salaries for performing services involved in the program, such as teaching or administrative tasks.

William Ross in Saunders' division will head the program.

Meanwhile, the impasse over the research training grant program remains unbroken. Benno Schmidt, chairman of the President's Cancer Panel, had another session at the White House Tuesday. He asked for the meeting to make still another pitch for training grants and for increased budgets throughout NIH.

A congressional source told *The Cancer Newsletter* that the failure of Senate and House conferees to reach agreement on the training grant bill (*The Cancer Newsletter*, April 19) does not mean the bill is dead. At least one more session will be held, and he indicated that a compromise is still possible.

Any compromise would force either Paul Rogers, chairman of the House Health Subcommittee, or his Senate counterpart, Edward Kennedy, to back down. There is no difference in the training grant section of the bill; the issue is the provision in the Senate version creating a national commission to oversee research involving human subjects. Rogers would like it removed entirely, but might agree to some language that would modify the commission's powers.

If the bill is allowed to die, full-scale revival of research training grants is out. HEW has hinted it will permit a "limited" number to be awarded but has not yet offered any public committment.

Industry Goes After Bigger Chunk Of NIH Business, Including Grants; NCI Favorable

Commercial firms engaged in biomedical research and allied support services have opened a drive to achieve parity with academic and not-for-profit institutions in competing for NIH research dollars—and they have received a favorable response at NCI and from talks with NIH Director Robert Stone and HEW Asst. Secretary for Health Charles Edwards.

The commercial firms have convinced NCI that they should not be frozen out of competition for awards in the new program grant system being devised to replace research contracts held by academic institutions.

NCI Director Frank Rauscher and his senior staff members came up with the program grant idea in answer to criticism that too much research money was going into contracts.

Since HEW policy prohibits for-profit organizations from receiving grants, NCI planned to limit the switchover to those research contracts held by institutions eligible to receive grants. This would have left the life sciences industry (as the commercial firms refer to themselves) with no chance to compete for new research jobs except for those renewals of contracts in the commercial sector. And they still would have to compete with the not-for-profit organizations for their own renewals.

It jsn't just the program grants that the industry is going after, however. "We see no reason why we should not be able to compete for 100% of NIH's research programs," an industry executive told *The Cancer Newsletter*. "Why shouldn't one of our scientists who has a good idea that should be pursued and a solid proposal have the same opportunity for a grant that a university scientist has?"

A top NCI official agreed. "We should break down these artificial barriers," he said. "The contract and grant mechanisms are just tools, not ends in themselves. If a commercial firm can do a particular job better or cheaper or faster, we should not penalize the government and the taxpayer by unnecessarily restricting ourselves."

Six commercial firms have organized a trade association, called the National Assn. of Life Sciences Industries, to present their message to the appropriate powers in Washington. They are soliciting memberships among the 100 to 200 similar firms around the country.

"We have three primary goals," said Donald Nielsen, president of Hazleton Laboratories, Vienna, Va., and one of the association organizers. "Number one: The opportunity to bid on 100% of NIH extramural spending. Number two: Representation on policy-making bodies. Number three: Equalization of cost factors in competition between industry, the universities, and the not-for-profit institutions."

To achieve the first goal, the association may align itself with those in academia who have felt that the grant and contract mechanisms should be replaced by a "research agreement" in which the degree of NIH control is determined by the nature of the project. NCI, at least, appears to be moving in that direction with its program grants.

The second objective, representation, also is acceptable to NIH. Look for some industry members to be named to advisory groups as vacancies occur. Recommendations for six vacancies on the National Cancer Advisory Board had already been made when the association submitted its request; the next vacancy might well be filled by an industry member.

The third goal, equalization of cost factors, could be a sticky one. The association will argue that non-taxpaying institutions can invariably underbid a business firm, all other factors being equal; and that other public funds—state, local, federal—subsidize those low bids by paying for facilities and sometimes salaries, items industry has to cover in its bid proposals.

The association can point to a precedent in Dept. of Defense policy that permits a factoring formula to be used in weighing contract proposals from the private and non-profit sectors.

Whether HEW, and especially the more hard-pressed NIH institutes, will recognize the merit of that argument is doubtful.

The six founding members of the association are, in addition to Hazleton, Electro-Nucleonics, Flow Labs, Microbiological Associates, Litton Bionetics and EG&G-Mason.

Tracor Could Earn $186,000 As Prime Contractor On Carcinogenesis Bioassay

One commercial firm that wasn't complaining last week was Tracor Jitco Inc., which landed the $6.6 million contract to manage NCI's carcinogenesis bioassay program. *(The Cancer Newsletter*, April 19*)*.

Tracor beat out four others for the prestigious job—Hazleton Labs, Microbiological Associates, EG&G Corp. and Illinois Institute of Technology Research, Inc. However, IITRI was eliminated after the first evaluation, and was never considered in the competition.

The job includes handling renegotiation of existing bioassay contracts with commercial firms in the carcinogenesis program as they come up for renewal. For that and all the other management tasks, Tracor could earn a maximum of $186,283 for the 15-month period beginning last March 1.

That may not seem like much compared with the similar award-based-on-performance contract NCI has with Litton-Bionetics to run the Frederick Cancer Center. Litton's contract will total nearly $11 million for the year ending next June 25, and its maximum award for the year was set at nearly $880,000. Although Tracor's contract totals more than half of Litton's, the maximum award is only 21% of that held out to Litton.

The major difference is that Tracor will be doing no research or production itself, with fewer people and facilities tied up.

The Tracor fee will not be based entirely on performance. It is guaranteed a fixed fee of $77,729. An additional $108,554 will be available, split into four rating periods with $27,138 each. A 10-member performance evaluation panel of NCI executives will recommend the award following the end of each period. NCI Director Rauscher can revise the recommendation, but his word is final—there is no appeal. No amount of money left from one period may be carried over to the next.

Dennis Dougherty is NCI's contracting officer for the program.

NCI has at least five and perhaps more contract programs it is considering switching to the prime contractor system (Battelle's toxicology contract and Tracor's are the only two at present). "We'll wait and see how these work out," Research Contracts Chief Carl Fretts said. "If it buys us what we are hoping for, and alleviates some of the work load on our limited staff, I'm sure we'll consider using it for other programs."

Some potential problems: Failure of the prime and subcontractors to get along with each other—they are competitors; friction between NCI project people and contractor's staff.

Cancer Control Awards $1.5 Million Grant For 3-Year Study By College Of Radiology

The American College of Radiology has received the first grant awarded by the Cancer Control Program, $1.5 million to evaluate existing methods of radiation treatment for cancer and to establish radiation treatment guidelines.

Simon Kramer of Thomas Jefferson University Hospital, Philadelphia, will direct the three-year project. A group of 24 radiation therapists, 50 radiotherapy residents, and 10 clinical physicists are being recruited to carry out the study.

The use of radiation therapy in the United States and Puerto Rico will be documented region by region, and criteria developed for optimal radiation therapy. Present practice will be compared with optimal care and necessary improvements identified.

Organizations influencing radiation care will be analyzed, such as those responsible for accreditation, medical insurers, and government agencies. Policies and programs to improve care will be formulated.

The investigation is an outgrowth of concern by radiotherapists and their professional organizations, including the American Society of Therapeutic Radiologists, that insufficient information is available to evaluate the quality of care given to cancer patients. This study may become a model for evaluating other methods of cancer treatment as well as for other disciplines of medicine.

Under the new grant, radiation facilities across the nation will be surveyed. Data will be gathered on the numbers of patients treated, by type of cancer, and the availability of professional and technical staff, space, equipment, financial and economic factors, services (such as diagnostic radiology and nuclear medicine), and patterns of referral. Questionnaires, on-site evaluations of treatment records, and examinations of

the relationship between third-party carriers and treatment institutions will be utilized.

The care of patients with 15 types of cancer for which there is substantial concensus about radiation treatment will be studied. Care will be reviewed in various medical institutions, metropolitan areas and states with heavy or sparse populations. The regional accessibility of radiation will be investigated. Patients, physicians, and institutions will not be identified in the report. It is not intended as an individual audit, but as a system of identifying patterns of care.

NCI Clamps Down On Site Visits, Announces New Policy To Reduce Number, Improve Quality

"Members of site visit teams sometimes receive their copies of the grant application when they arrive at their hotel, the night before they are to make their visit. . .Applicants have complained that the visitors often are obviously unfamiliar with their applications, don't ask relevant questions. . ."

That was one of the reasons prompting J. Palmer Saunders, director of NCI's Div. of Research Resources & Centers, to put the brakes on premature and perhaps unnecessary site visits. Another reason is pressure by HEW to reduce costs incurred by the NIH peer review system, and especially to cut down on travel.

Saunders recently issued a memo listing guidelines for a new policy on site visits.

"The visits have seriously usurped the time and energy of our consultants whose first responsibilities lie in their home-based activities," the memo said. "The increasing numbers of applications have, moreover, led to a serious depletion of the available pool of expert consultants. Finally, we do not have a large enough number of executive secretaries. Most of them, during the time preceding a meeting, must go on two to three visits a week."

Here's the new policy, effective with the next round of applications:

–1. Staff review–The executive secretary, in collaboration with the program director to whom the application has been assigned, reviews the proposal for obvious omissions. If he recognizes such, he solicits completion from the applicant by correspondence or telephone. The grants management specialist, preparing the informational summary, proceeds the same way. If the executive secretary, program director, or grants management specialist judges the omissions to be serious enough, the executive secretary may elect to defer the application for additional information.

–2. Committee review–In general, the application goes directly to the committee without a preceding site visit. The committee may judge the application to be so clearly of high quality or so clearly of poor quality that it can arrive during the meeting at a recommendation for approval or disapproval.

–The committee may vote to defer its recommendation to the next meeting. This action would be a diagnostic one, directed at soliciting only the information needed for a competent and equitable recommendation. The committee should consider the specific factual and evaluative information needed and how to obtain it. If the executive secretary estimates that he cannot get it by correspondence or telephone, the committee may then vote for a site visit.

–In preparing for a site visit, the committee selects during the meeting which of its members are to participate, indicates the individuals or competencies for ad hoc augmentation and, of most importance, specifies the factual and evaluative information needed. The size of the visiting teams of consultants and staff should be limited to what is essential.

–Reports of the visit should address themselves only to information and should exclude recommendations for disapproval or for approval with priority ratings. The committee makes these recommendations at its second review of deferred applications. The competence that the committee exercises, along with a careful weighing of strengths and weaknesses, determines the excellence of the review.

It was the last provision–which seems to prohibit site visitors from making recommendations for disapproval or approval and from assigning priority ratings–that aroused objections from various review groups.

"The memo raised a storm of protest among those I thought would be happiest about the new policy," Saunders admitted to members of the Clinical Investigating Reviewing Committee.

Told that the objections centered on the admonition against making recommendations, Saunders softened his position. "That was not intended to be a flat-out policy against recommendations by site visitors," he said. "Committees often reverse recommendations of the visiting team, for a number of valid reasons. But the team's recommendations frequently are made known to the applicant, who thinks he has a grant only to find out later he doesn't.

"The new policy requires only that recommendations be revealed only to the committee."

Cancer Mortality By County For 1950-69 Now Available From GPO; Price–$9

The NCI compendium, "U.S. Cancer Mortality by County: 1950-1969," is now available from the Government Printing Office, Washington, D.C. 20402. The price is $9.

The 729-page volume was prepared by Thomas J. Mason and Frank W. McKay of NCI's epidemiology branch. It lists the total number of cancer deaths for each of 34 body-sites according to sex and race for each county.

Private Sector Still Valuable To National Cancer Program, ACS Research Chief Says

"The need for more private sector activity will be even greater as the incidence of some cancers increases and as more cured cancer patients are returned to their communities," Arthur I. Holleb, senior vice president for medical affairs and research of the American Cancer Society, told members of the National Cancer Advisory Board.

"Although the American Cancer Society plays an important role in funding research projects across the country, its contribution is numerically overshadowed by the relatively large sums now available from the National Cancer Institute," Holleb said. "One may even wonder why there is a need for the American Cancer Society at all."

Holleb immediately refuted that thought by pointing to ACS' annual research budget of $25 million which he said "must continue because it assures the investigator of at least two resources—private and federal—so that he need not rely solely on the government for support."

He also referred to the society's extensive professional educational programs; information and counseling programs for patients; rehabilitation programs for the laryngectomy, mastectomy and colostomy patients; and efforts to protect the public "from the unscrupulous who promote unproven methods of treatment."

ACS also disseminates public-education messages on the early warning signs of cancer, value of earlier diagnosis and treatment, and the dangers of potentially carcinogenic hazards, Holleb pointed out.

ACS conducts its own intramural epidemiologic studies aimed at pinpointing environmental threats, Holleb said. Non-environmental factors, including heridity, are also being studied.

"The opportunity now exists for the federal government with its expanded funding and the private sector with its volunteer resources to work hand in glove," Holleb said. "A joint effort is essential to success and is best exemplified in the 27 breast cancer detection demonstration projects.

"The society initiated the idea, intending to have only 12 breast cancer detection projects. . .With the splendid cooperation of NCI, particularly Dr. Rauscher and Dr. Nat Berlin, there are now 27 projects to evaluate about 300,000 women. . .Enthusiasm generated among clinicians and ACS volunteer support is almost beyond description."

NIH Seeks Method For Allocating Research Funds, Determine Economic Impact By Disease Category

NIH is initiating twin studies aimed at developing methodology for allocating research funds by disease categories and to determine the economic cost of each disease category and health problem. The agency has issued RFPs for contracts to perform the studies (see below).

The trend by Congress to allocate funds by disease categories and to give statutory emphasis to some health problems has created a backlash in the scientific and health communities. Some scientists feel that health problems, including cancer, could be sooner and more effectively ameliorated if the big research programs were not channeled along categorical lines. Some HEW executives agree with that view.

The studies proposed by NIH possibly could turn up evidence useful to both sides in the controversy. The first, to find a methodology for allocating research funds by disease categories, certainly could be used to limit the growth of the National Cancer Program, depending on how the study is designed and who performs it.

On the other hand, the second study—to determine the economic impact of each category—could provide a powerful argument in favor of expanded cancer research. NCI has estimated that cancer results in an economic loss to the nation of $15 billion a year, not including treatment costs. It is doubtful if any other disease category, except heart disease, can be substantiated as causing losses close to that figure.

The study could be used to justify greater expenditures in many other disease categories, and especially heart disease.

Benno Schmidt, who helped lead the fight to establish the National Cancer Program, argued to representatives of heart and other health problems that "the next best thing to getting a raise yourself is for your neighbor to get one." Increased spending for cancer research would open the door for other programs to get bigger budgets, his theory went.

It didn't quite work out that way, which is why Schmidt has taken up the fight for increased funding for all NIH.

To receive either or both RFPs, write to Research Contracts Branch, Office of Contracts & Grants, Attn. David Sinicrope, NIH Bldg. 31, Room 1B34, Bethesda, Md. 20014.

RFP NIH-OD-74-23

Title: *Feasibility study to develop methodology for allocating national expenditures for biomedical research by disease categories and health problems.*

Deadline: *June 3, 1974*

RFP NIH-OD-74-22

Title: *Trends in the economic cost of disease and illhealth and their relationship to biomedical innovation and to national biomedical research.*

Deadline: *June 3, 1974*

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Contract Sections for the Cause & Prevention and Biology & Diagnosis Divisions are located at: NCI, Landow Bldg, NIH, Bethesda, Md. 20014; for the Treatment and Control Divisions at NCI, Blair Bldg., 8300 Colesville Rd., Silver Spring, Md. 20910. All requests for copies of RFPs should cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-43751

Title: *Operation of an animal disease diagnostic laboratory*

Deadline: *On or about May 30, 1974 (The RFP will list the exact date)*

NCI is seeking proposals from qualified contractors for the operation of an animal disease diagnostic laboratory including research into improvement of diagnostic techniques. The scope of this effort will consist of a major service phase.

This phase will be concerned with the operation of a salmonella Spp. and pseudomonas Spp. diagnostic effort for monitoring all rodent strains, stocks, and species maintained by the Div. of Cancer Treatment animal resources; monitoring of tumor stocks microbiologically, as required; provision of diagnostic services for unusual conditions; provision of assistance in control and prevention of epizootics.

It is estimated that these diagnostic services will require processing 2,000-3,000 fecal specimens per year as well as performing 500-1,000 special tests per year. The research phase of the project will require studies in support of the Div. of Cancer Treatment screening program.

These studies will be directed towards the implications of microbiological contaminants in tumors and hosts.

Contract Specialist: Joe Kerner
301-427-7470
Cancer Treatment

CONTRACT AWARDS

Title: Preliminary planning for a cancer access information system for the Denver region

Contractor: Colorado Regional Cancer Center, Inc., $29,300

SOLE SOURCE

Proposals are listed here for information purposes only. RFPs are not available.

Title: Fractionation and isolation of anti-tumor substances.

Contractor: Research Triangle Institute, Research Triangle Park, N.C. (continuation)

Title: Curricular guidelines for cancer education in health professional schools

Contractor: Assn. of American Medical Colleges, American Assn. of Dental Schools

Title: Immunologic study of RNA (type C) viruses

Contractor: Scripps Clinic and Research Foundation, La Jolla, Calif.

Title: Study of effects of carcinogens on the in vitro synthesis of complement components

Contractor: The Children's Hospital Medical Center, Boston (continuation)

Title: Breast cancer demonstration projects

Contractors: Stella and Charles Guttman Breast Diagnostic Institute, NYC; Mountain States Tumor Institute, Boise, Idaho; Good Samaritan Hospital, Portland, Oregon; Virginia Mason Research Center, Seattle, Wash.; Cancer Research Center, Columbia, Mo.

MEETINGS

NCI advisory group meetings frequently are closed, usually for review of contract and grant applications. Times scheduled as open will be shown with each listing, but these sometimes are changed.

Cancer Treatment Advisory Committe, NIH Bldg 31, conference room 10, April 29, open 9 a.m.-5 p.m.

Lung Cancer Segment Advisory Group, NIH Bldg 31, conference room 3, April 29, open 3-4 p.m.

Cancer Special Programs Advisory Committee, NIH Bldg 31, conference room 8, May 9-10, open May 9 9-10 a.m.

Cancer Centers Review Committee, NIH Bldg 31 conference room 6, May 17-18, open May 17, 9-10 a.m.

President's Cancer Panel, NIH Bldg 31, conference room 5, May 20, 9:30 a.m.-12, all open.

Virus Cancer Program Scientific Review Committee, Landow Bldg, conference room C418, May 29, open 9-10 a.m.

Cancer Control Education Review Committee, NIH Bldg 31 conference room 3, May 31, open 8:30-9:30 a.m.

The Cancer Newsletter—*Editor* JERRY D. BOYD

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